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STRIKER, STRIKER & STENBY
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Huntington, NY 11743

EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,318

Applicant(s)

SADAIE, TAMIKO

Examiner

Lora E. Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The reply and Request for Continuing Examination received 9/6/05 amending withdrawn claims 6 and 8, canceling claims 9-14, and adding claims 15-19 is acknowledged. Claims 1-5, 7, and 9-14 are/remain canceled, and claims 6 and 8 remain withdrawn. Claims 15-19 are currently under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Applicant cannot rely upon the foreign priority papers (JP 2003-44321) to overcome any art rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Specification

The examiner notes the new abstract and the cancellation of the new matter. The objections to the specification are withdrawn in light of the reply received 9/6/05.

Claim Objections

Claim 15 is objected to because of the following informalities: The spelling of the names of the microorganisms is queried, since the spelling of some genus and species names is different from the spelling in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 15-19 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically *Methylosinus trichosporium*. It is noted that an ATCC deposit number is provided for said materials, but the ATCC has no record of any organism's being deposited under the number 35070. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (p.9), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Applicant has alleged that the substitution of "ATCC 35070" for "ATCC 49242" was "inadvertent" because of, for example, reversed digits or a misreading of a list (Remarks, page 10). Applicant requests that the examiner point out a way to correct the error (Remarks, page 11).

As discussed on the most recent Office action, because the numbers do not resemble each other in any way, the examiner cannot reasonably assume that a typographical error was made. The situation can only be remedied by the filing of a continuation-in-part application with the desired number recited in the specification.

Claims 15-19 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the **claimed invention**.

Claim 15 is drawn to a composition made by culturing "organic waste liquid" using particular steps and comprising particular fungi and bacteria. The claim further requires that the composition made by the recited method comprise particular strains fungi and bacteria that have been deposited with the ATCC. A composition comprising the claimed strains is simply not supported by the specification as filed.

The specification describes a process wherein "domestic sewage" is aerated, thus allowing the natural flora to grow (page 13), and the declaration signed by applicant on 9/30/03 is in Japanese and gives the applicant's citizenship and mailing

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address as Japanese. It is therefore assumed that the domestic sewage recited in the Examples is also Japanese. A search for the recited strain numbers in the ATCC database, however, shows that none of the claimed strains are native to Japan (reference provided in prior Office action) Four are native to the United States (ATCC 23107, ATCC 14909, ATCC 31898 and ATCC 14580), two are native to India (ATCC 49305 and ATCC 700366), and one is native to the Philippines (ATCC 90364).

The composition comprising fungi and bacteria is disclosed on page 15 of the specification as being produced by culturing Japanese domestic sewage as described on page 13 of the specification. Since none of the claimed strains of fungi or bacteria are present in Japanese domestic sewage (or, indeed, sewage from any single location on Earth), the applicant cannot have been in possession of a process that comprises culturing sewage as disclosed and yields the precise composition of claim 15.

In Table 1 at page 14, applicant characterizes the organisms isolated and identified using the method described on page 13; no accession numbers are recited in Table 1. In short, the specification does not describe a composition comprising the **claimed** strains of bacteria and fungi. Applicant was not in possession of the composition as claimed at the time of filing.

Because claims 16-19 depend from claim 15, they must also be rejected under 35 U.S.C. § 112, first paragraph, because they have not been adequately described in the specification as filed.

Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites a composition "comprising a fungi and symbiotic bacterial group mixture", which is confusing. The term "symbiotic bacterial group mixture" is not defined in the specification or within the art. In addition, it is not clear to what element the word "symbiotic" refers. Clarification is required. Because claims 16-19 depend from indefinite claim 15 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 16 recites "as defined" twice. Clarification is required.

Claim 17 is confusing in that it recites "applying the supernatant to a cellulose substrate forming a culture bed", which is confusing. It is not clear to what process or composition the word "forming" refers. Clarification is required.

Claim 17 also recites the term "weakly aerobic conditions", which is not defined in the specification or the art. Clarification is required.

Claim 19 is confusing because it is not clear whether the recited functions are inherent properties of the claimed microorganisms or otherwise. Clarification is required.

Claim 19 is further confusing in that it recites numerous process steps but is drawn to a composition. It is not clear whether the claim is drawn to a product or to a process of use. Clarification is required. The claim has been interpreted as reading on a composition with various inherent properties.

Claim Rejections - 35 USC § 102

Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton (1993, U.S. Patent 5,240,611; reference B). The claims are drawn to a composition produced by aerating organic waste liquid in a microaerobic environment to form a supernatant and a sediment and separating the sediment from the supernatant. The composition is claimed to comprise specific strains of numerous fungi and bacteria. In some dependent claims, the fungi and bacteria have specific functions. In some dependent claims, the organic waste liquid is sewage. In some dependent claims, the composition is dried. In some dependent claims, the composition comprises nitrate.

Burton teaches a compost that comprises bacteria and fungi, as well as nitrate and collagen, and that decomposes organic waste (column 2, line 56, through column 3, line 10). The compost (Figure 1, item **32**) of Burton is placed into a sealed tank (item **22**) on a charcoal filter (item **33**) and contacted with liquid waste; the waste is separated from the compost by the filter and the compost dries until the next use.

Claims 15 and 19 are also rejected under 35 U.S.C. 102(b) as being anticipated by Sumi (1979, U.S. Patent 4,179,365; reference A). The claims are drawn to a composition produced by aerating organic waste liquid in a microaerobic environment to form a supernatant and a sediment and separating the sediment from the supernatant. The composition is claimed to comprise specific strains of numerous fungi and bacteria. In some dependent claims, the fungi and bacteria have specific functions.

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Sumi teaches an activated sludge made by aerating phenolic resin manufacturing wastewater at 0.1-1ppm dissolved oxygen (column 3, lines 50-56), then sedimenting an activated sludge from treated water (Example). Sumi further teaches that activated sludge comprises bacteria and fungi (column 2, lines 21-39).

Claims 15-19 are also rejected under 35 U.S.C. 102(b) as being anticipated by Higa (1997, U.S. Patent 5,591,634; cited previously) in light of Kickuth et al. (1988, U.S. Patent 4,793,929; cited previously). The claims are drawn to a composition as described above.

Higa teaches a composition comprising the mold fungi *Aspergillus japonicus*, *Aspergillus oryzae* and *Mucor hiemalis* and the bacteria *Streptomyces albus*, *Streptoverticillium baldaccii*, *Nocardia asteroides*, *Micromonospora chalybeata*, *Rhodopseudomonas sphaeroides*, *Rhodospirillum rubrum*, *Chromatium okenii*, *Lactobacillus bulgaricus*, *Propionibacterium freudenreichii*, *Pediococcus halophilus*, *Streptococcus lactis*, and *Streptococcus faecalis* (Example 1). Higa further teaches that said composition can grow under "closed and airtight conditions" (column 6, lines 8-14) and can subsist on "kitchen waste" for at least 14 days (Example 11).

Kickuth et al. demonstrate the conversion of ammonia naturally present in sewage water to nitrate (column 2, line 60-column 3, line 4 and column 10, lines 12-45). With regard to the presence of "cellulose substances" in the environment of claim 4, paper is commonly found in domestic sewage.

Claims 15-19 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." Therefore, the process steps within claim 15 have been considered only to the extent that they affect the structure of the composition. In view of the prior art, it is not clear what steps in the claimed method would yield a product patentably distinct from the products of the prior art. As such, the claims have been interpreted as being drawn to a composition comprising numerous bacteria and fungi, made by any process.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. **The patentability of a product does not depend on its method of production.** If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable **even though the prior product was made by a different process.**" *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' mixture differs, and if so to what extent, from the mixture discussed in Sumi, Burton, and Higa. Accordingly, it has been established that the prior art mixtures, which comprise numerous bacteria and fungi and are disclosed as having utility in waste treatment, demonstrate a reasonable probability that they are either identical or sufficiently similar to the claimed mixture that whatever differences exist are not patentably significant.

Indeed, Kulpa et al. (1989, U.S. Patent 4,803,166; reference C) teach that over 50 species of fungi and over 300 strains of bacteria have been found in various

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activated sludges (column 5, lines 50-53). Many, if not all, of the claimed species are known in the art to be present in activated sludges; for example, Sweeny (1977, U.S. Patent 4,005,011; reference D) teaches that *Pseudomonas* spp. and *Flavobacterium* spp. are present in activated sludge and are useful in waste treatment (column 3, lines 46-56). Therefore, the burden of establishing novelty by objective evidence is shifted to applicants.

Merely because a characteristic of a known mixture, in this case the presence of various specific strains of bacteria and fungi, is not disclosed in a reference does not make the mixture patentable. The instantly claimed mixture possesses inherent characteristics which might not be displayed in the tests used the reference. The mere fact that the instantly claimed mixture comprises microorganisms assigned a particular genus, species, and strain designation does not render the composition patentable. Clear evidence that the mixtures of the cited prior art do not possess a critical characteristic that is possessed by the claimed mixture would advance prosecution and might permit allowance of claims to applicants' mixture.

Applicant alleges that the eight microbes recited in claim 15 "cooperate in a special way to decompose organic waste while deodorizing it" (Remarks, page 16). Applicant urges that "objective evidence should not be required until the [Office] provides a reference that teaches a mixture of microorganisms that contain a reasonable number of at least similar microorganisms" (Remarks, page 18). Applicant further alleges that because the composition of Higa comprises yeast, it is not

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appropriate prior art against the instant claims (Remarks, page 18). Finally, applicant alleges that the mixture of Higa is grown under “completely anaerobic conditions”, while the instantly claimed mixture is grown in an environment in which the oxygen concentration is “1 ppm or less” (Remarks, page 18). These arguments have been fully considered, but they are not persuasive.

M.P.E.P. § 2112 reads, “The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.” Something that is old does not become patentable upon the discovery of a new property, use, or application. The core of applicant’s arguments is an assertion that the invention represents the identification of a new property of a composition, namely the manner of cooperation among the microorganisms therein. If this is the case (which the examiner does not concede), the composition is not necessarily patentable simply because of such a discovery.

Applicant’s statement regarding the standard for requiring objective evidence is confusing. It is not clear what applicant would consider “a reasonable number” of microorganisms, or what sort of similarity would satisfy applicant’s requirement. The microbes of the cited prior art are found in sewage, as are the instantly disclosed microbes. The microbes of the cited prior art comprise bacteria and fungi and have activity in waste treatment, as do the instantly disclosed microbes. The mere fact that applicant has assigned a different name or strain number to the components of the composition does not render it patentable.

Applicant's arguments regarding the presence or absence of yeast in the composition are misplaced; the claims are silent as to yeast. In fact, the composition is claimed as "comprising" eight species. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). See M.P.E.P. §2111.03. The instant claim encompasses all compositions that comprise at least the recited bacteria and fungi.

Finally, the examiner does not dispute that the mixture of Higa was prepared under anaerobic conditions; the instant claims, however, do not exclude anaerobic environments. The claims merely require 1 ppm oxygen or less; zero oxygen is certainly less than 1 ppm oxygen. Applicant's assertion that "1 ppm or less" does not include "0 ppm" is, quite simply, incorrect.

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (M.P.E.P. § 714.02 and § 2163.06). Due to the procedure outlined in M.P.E.P. § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

leb



IRENE MARX
PRIMARY EXAMINER